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| EXAMINER | |
|---|---|
| CHOI, FRANK I | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/997,663 | MEISNER, LORRAINE FAXON | |
| | Examiner | Art Unit | |
| | Frank I. Choi | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *1/16/2008 and 11//28/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20080116,20071128*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/2007 and 1/16/2008 has been entered.

### *Drawings*

The drawings are objected to because Figure 4 is of poor quality in that the differences between the copy of the photo of before treatment and the photo of after treatment cannot be seen. Rule 1.84 states in part that -

> (b) Photographs .—
> (1) Black and white . Photographs, including photocopies of photographs, are not ordinarily permitted in utility and design patent applications. The Office will accept photographs in utility and design patent applications, however, if photographs are the only practicable medium for illustrating the claimed invention. For example, photographs or photomicrographs of: electrophoresis gels, blots (e.g., immunological, western, Southern, and northern), auto-radiographs, cell cultures (stained and unstained), histological tissue cross sections (stained and unstained), animals, plants, in vivo imaging, thin layer chromatography plates, crystalline structures, and, in a design patent application, ornamental effects, are acceptable. If the subject matter of the application admits of illustration by a drawing, the examiner may require a drawing in place of the photograph. The photographs must be of sufficient quality so that all details in the photographs are reproducible in the printed patent.
> (2) Color photographs . Color photographs will be accepted in utility and design patent applications if the conditions for accepting color drawings and black and white photographs have been satisfied. See paragraphs (a)(2) and (b)(1) of this section.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25-27 requires that of the at least 10% (w/v) ascorbic acid that "at least 10% (w/v) of the ascorbic acid" be pretreated ascorbic acid. There is no support for the limitation "at least 10% (w/v) of the ascorbic acid". Paragraph 00028 of the Specification states that "pretreated" ascorbic acid is ascorbic acid that has been dissolved in water at a relatively high temperature to form a concentrated ascorbic acid solution. Said paragraph further indicates that at least about 10% of the ascorbic acid present may be pretreated ascorbic acid. Based on said

definition, the amount of ascorbic acid is based on the weight of the total amount ascorbic acid in the composition not weight/volume. As such, there is no support for the above limitation.

Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25, the preamble states as follows: "A composition having a pH of about 3.5 to about 4.1". However, the only components identified in the body of the claim are water, glucosamine and ascorbic acid. According to the Merck Index (9th Ed. 1976), ascorbic acid in water has a pH of 3 at 5 mg/ml and a pH of 2 at 50 mg/ml. Since the minimum of ascorbic acid claimed exceeds the 50 mg/ml, it is unclear how the composition can have a pH of about 3.5 to about 4.1. The Examiner suggests that a limitation with respect to the pH be set forth in the body of the claim. Since claims 26 and 27 are dependent on claim 25 and do not correct the ambiguity said claims are also rejected.

In claim 26, the composition of claim 25 is made by adjusting the pH of the mixture comprising water and pretreated ascorbic acid to about 3.8 to about 4.0 to provide a pH-adjusted mixture and admixing the pH-adjusted mixture and the glucosamine, which renders the claim indefinite. It is unclear how the composition of claim 25 can be prepared from the method in claim 26 as the pH range in claim 26 is narrower than the pH range in claim 25. If the Applicant intended to further limit the pH range in claim 26 then the claim should have indicated that the pH range of the composition is about 3.8 to about 4.0 and then set forth the method step limitations.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US Pat. 5,804,594) in view of Schinitsky et al. (US Pat. 4,938,969), Herstein (US Pat. 5,902,591), Bassford et al. (US Pat. 2,517,276), Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557.

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising glucoseamine (about 3 to 17 weight percent) and ascorbic acid (about 5 to 50 weight percent) (Column 4, lines 62-68, Column 5, lines 1-24, 58-68, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that glucoseamine assists in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22).

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4,

lines 34-45, Claims 1, 2). A formulation is disclosed in Table 1 containing among other ingredients, water (58.85 %), glycerine, propylene glycol, zinc sulfate (2.08 %), ascorbic acid (10.06%) and tyrosine and a control formulation is disclosed which contains the same ingredients as set forth in Table 1 except that it does not contain tyrosine or ascorbic acid (Column 3, lines 8-46, Column 4, lines 1-27).

Herstein discloses that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 10, lines 6-17).

Bassford et al. disclose methods of purifying ascorbic acid in which one of the steps includes dissolving ascorbic acid in distilled water at 60 degrees Celsius, for example 105 g in 140 cc, 100 g in 140 cc, 30 g in 30 cc (Column 4, lines 16-33, Column 5, lines 60-76, Columns 6-8). It is disclosed that when preparing pharmaceutical compounds it is generally advisable to effect the final purification by crystallizing a first crop of pure material in the conventional manner that is disclosed as being Experiment B (Column 3, lines 30-35, Column 5, lines 60-68, Column 6, lines 39-76, Column 7). It is disclosed that after heating to about 60 degrees Celsius the solution is cooled, for example to 15 degrees Celsius (Column 4, lines 15-30).

Ptchelintsev discloses that topical application of an antioxidant, such as ascorbic acid, is effective in reducing the redness, flushing and blushing associated with either sensitive skin or rosacea (column 4, lines 35-56). It is disclosed that the amount of antioxidant can range from 0.001 wt% to about 100wt% but that for practical reasons creams, emulsions, lotions or gels would require concentrations of antioxidants that are less than 50 wt% (Column 6, lines 49-68).

EP 0 771 557 discloses the use of ascorbic acid, preferably in the amount of 1 to 20% by weight, for treatment of acne, preferably at a pH of 2 to 5, particularly at a pH of 4 (Page 2, lines 30-58, Page 3, lines 1-7).

The prior art discloses topical compositions containing ascorbic acid (5-50 wt. %), glucosamine (3-17 wt. %) and water. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose that at least 10% of the ascorbic acid is pretreated by dissolving ascorbic in water at a temperature of between about 60-90 degrees Celsius and cooling to below about 40 degrees Celsius and a pH of about 3.5 to about 4.1. However, the prior art amply suggests the same as the prior art discloses that a pH of 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin. Also, the prior art discloses that ascorbic acid is effective in the treatment of rosacea, acne and hypersensitivity conditions. Further, the prior art discloses the preparation of pure ascorbic acid for pharmaceutical use in which one of the steps includes dissolving ascorbic acid in water at 60 degrees Celsius and cooling, for example to 15 degrees Celsius. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid according to the process in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes. Also, one of ordinary skill in the art would have expected that the ascorbic acid would be effective in topically treating rosacea, acne and hypersensitivity conditions. Finally, since the prior art discloses a pH range that encompasses the pH range of

about 3.8 to about 4.0 and the presence of glucoseamine, it would have been well within the skill of one of ordinary skill in the art to adjust an aqueous solution containing ascorbic acid to the desired pH and mixing the desired amount of glucosamine in the composition. See In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons of record and the further reasons below.

The Supreme Court in KSR International Co. v. Teleflex Inc., held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes,

and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The Applicant argues that the prior art does not disclose or suggest the claimed composition. However, as indicated above, the prior art discloses the pH range, the combination of water, glucoseamine and ascorbic acid in amounts overlapping that claimed and pretreatment of ascorbic acid by dissolving the ascorbic acid water at a temperature that falls within the claimed temperature range, in a concentration that falls within the claimed concentration range and cooling to a temperature that falls within the claimed temperature range. Further, the prior art provides motivation to combine water, glucosemine and ascorbic acid, i.e. treatment of skin

and removal of wrinkles, pH range, i.e. facilitate absorption of ascorbic acid and pretreatment, i.e. obtaining a purified form of ascorbic acid for pharmaceutical uses.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US Pat. 5,804,594) in view of Schinitsky et al. (US Pat. 4,938,969), Darr et al. (US Pat. 5,140,043), Bassford et al. (US Pat. 2,517,276), Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557.

Murad is cited for the same reasons as above and incorporated herein to avoid repetition.

Schinitsky et al. is cited for the same reasons as above and incorporated herein to avoid repetition.

Darr et al. disclose that ascorbic acid's activity as anti-oxidant has beneficial pharmaceutical effects with regards to adverse changes in the skin brought about by environmental conditions such as UV exposure but that ascorbic acid is unstable (Column 1, Column 2, lines 1 –55). It is disclosed that a pH of no more than about 3.5 ensures that greater than 82% of the ascorbic acid remains in the protonated, uncharged form and facilitates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule (Column 3, lines 17-33, Column 4, lines 7-18, claims 1-42). It is disclosed that at even at a pH of 4.5, a 5% solution of ascorbic acid remains quite stable and that at a pH of 4.2, 5% ascorbic acid remained stable (Column 5, lines 1-27). It is disclosed that carriers for topical application useful in practicing the invention include but are not limited to alkylene glycols, such as propylene glycol, or alkylene glycols in combination with hydroxyalkylcellulose derivatives, such as hydroxypropylcelulose,

and glycerol (Column 3, lines 33-53). It is disclosed that ascorbic acid can be present in amounts of at least about 1 wt. %, preferably from about 3 to 20 wt.%, and more preferably about 5 to 10 wt.% in water and a carrier for topical application (Column 3, lines 18-33).

Bassford et al. is cited for the same reasons as above and is incorporated herein to avoid repetition.

Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557 are cited for the same reasons as above and is incorporated herein to avoid repetition.

The prior art discloses topical compositions containing ascorbic acid (5-50 wt. %), glucosamine (3-17 wt. %) and water. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose that at least 10% of the ascorbic acid is pretreated by dissolving ascorbic in water at a temperature of between about 60-90 degrees Celsius and cooling to below about 40 degrees Celsius and a pH of about 3.5 to about 4.1. However, the prior art amply suggests the same as the prior art a pH of about 3.5 and that at pHs of 4.2 and 4.5, a 5% solution of ascorbic acid remained stable. Also, the prior art discloses that ascorbic acid is effective in the treatment of rosacea, acne and hypersensitivity conditions. Further, the prior art discloses the preparation of pure ascorbic acid for pharmaceutical use in which one of the steps includes dissolving ascorbic acid in water at 60 degrees Celsius and cooling, for example to 15 degrees Celsius. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic

acid according to the process in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes. Also, one of ordinary skill in the art would have expected that the ascorbic acid would be effective in topically treating rosacea, acne and hypersensitivity conditions. Finally, since the prior art discloses a pH that falls within or is sufficient close to about 3.8 to about 4.0 and the presence of glucoseamine, it would have been well within the skill of one of ordinary skill in the art to adjust an aqueous solution containing ascorbic acid to the desired pH and mixing the desired amount of glucosamine in the composition. See In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,217,914 in view of Bassford et al., Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557.

Claim 7 of said US Patent discloses a topical composition comprising at least about 5% (w/v) ascorbic acid, water, having a pH which is adjusted to about 3.6 to about 4.1 wherein at least about 10 wt% of the total ascorbic acid is pretreated ascorbic acid and the pretreated ascorbic acid is produced by dissolving at least about 20% (w/v) ascorbic acid in water at 60 to 90 degrees Celsius, where the composition further contains glucoseamine.

Bassford et al., Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557 are cited for the same reasons as above and is incorporated herein to avoid repetition.

The US patent claims the above composition. The difference between the claimed composition and the claims of the present application is that claim 7 of the US Patent does not expressly disclose cooling the pretreated solution to less than about 40 degrees Celsius or treatement of rosacea or acne. However, the prior art amply suggests the same as the prior art discloses that ascorbic acid is effective in the treatment of rosacea, acne and hypersensitivity conditions. Further, the prior art discloses the preparation of pure ascorbic acid for pharmaceutical use in which one of the steps includes dissolving ascorbic acid in water at 60 degrees Celsius and cooling, for example to 15 degrees Celsius. As such, it would have been

well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid according to the process in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes. Also, one of ordinary skill in the art would have expected that the ascorbic acid would be effective in topically treating rosacea, acne and hypersensitivity conditions.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claim 7 of US Pat. 6,217,914 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 25, 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 14, 20 of U.S. Patent No. 6,444,699 in view of Setnikar et al.

Claims 6,14,20 of said US Patent disclose a composition having a pH of 3.6 to 4.2, water, 5 to 25 (w/v)% pretreated ascorbic acid and an aminosugar anti-inflammatory compound. The term "pretreated" is defined by the Specification to mean ascorbic acid which as been dissolved in water at about 60 to about 90 degrees Celcius to form a concentrated solution which contains at least 20% (w/v) ascorbic acid and cooled to below about 40 degrees Celsius (Column 5, lines 10-26). Setnikar et al. disclose that glucosamine is an aminomonosaccharide having a pharmacological therapeutic index with respect to antiinflammatory activity that is comparable

or superior to that on known non-steroidal anti-inflammatories (Abstract). The difference between the claims of said US Patent and the claims of the present Application is that the claims of said US Patent do not disclose glucosamine as the aminosugar anti-inflammatory compound. However, the prior art amply suggests the same as the prior art disclose that glucosamine is an aminosugar and that it has anti-inflammatory activity. As such, one of ordinary skill in the art would expect that glucosamine would be suitable for use as an aminosugar anti-inflammatory compound.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claim 6, 14, 20 of US Pat. 6,444,699 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
2/29/08

/John Pak/
Primary Examiner, Art Unit 1616